PROGRAMME

Chairpersons: **Kerstin Westermark (COMP, EMA) & Yann Le Cam (EURORDIS)**

9:00 – 9:10: *Welcome address* ***(Yann Le Cam, EURORDIS)***

9:10 – 9:40: "What mechanism could be created for a European evaluation of the relative efficacy / relative effectiveness of orphan drugs (CAVOD)?" **- Pascale Augé (Ernst &Young) – presented by Stéphanie Daireaux (Ernst &Young) and Georgios Margetedis (European Commission/ EAHC)**

9:40 – 10:10: "The European CAVOD mechanism as an opportunity for HTA agencies to enhance their collaboration" **- François Meyer (EUnetHTA)**

10:10 – 10:40: "Industry viewpoint on the implementation of the CAVOD process" **- Wills Hughes-Wilson (Chair, Joint European Industry Task Force on Orphan Medicinal Products & Rare Diseases)**

10:40 – 11:10 - COFFEE BREAK

11:10 – 11:40: "How would the CAVOD mechanism impact EMA's work and what would the relationship be with the present EMA committees?" **- Hans-Georg Eichler (EMA)**

11:40 – 12:10: "How can patients contribute to the CAVOD mechanism?" **Fabrizia Bignami (EURORDIS)**

12:10 – 13:00: Panel discussion: Speakers and panel members : **Ad Schuurman (MEDEV) & Antoni Montserrat (European Commission/DG Health & Consumers)**

Chairpersons: **Pascale Augé (Ernst & Young) & Georgios Margetidis (EC/EAHC)**

14:00 – 14:15: **Introduction to the parallel breakout sessions and presentation of the 4 discussion topics**: Pascale Augé, Ernst & Young

14:15 - 15:30: Parallel Breakout Sessions

1) Activities of the CAVOD process and practicalities for the preparation and endorsement of documents prior to, and at the time of, the positive opinion of the CHMP and at Marketing Authorisation
   Rapporteur: Meindert Boysen, NICE -*Facilitator*: Stéphanie Daireaux, Ernst & Young
2) Organisation and infrastructures needed to implement the CAVOD mechanism
   Rapporteur: Yann Le Cam, EURORDIS - *Facilitator*: Georgios Margetidis, EC/EAHC
3) Discussion around the European Research Plan (ERP): timelines, content, implementation and follow-up
   Rapporteur: Hans-Georg Eichler, EMA - *Facilitator*: Pascale Augé, Ernst & Young
4) Activities in the CAVOD process and practicalities for the preparation and endorsement of the "Clinical Evidence Report"
   Rapporteur: Wills Hughes-Wilson, Joint European Industry Task Force - *Facilitator*: Hicham Naim, Ernst & Young

15:30 – 16:15: Feedback from the parallel groups presented by the 4 rapporteurs
16:15 – 17:00: Discussion